DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 2006

Mr. Eric Varty
Research and Development Manager
Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Re: K024015 – Supplemental Validation Submission
Trade/Device Name: See Enclosed List
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NLM
Dated: December 3, 2002
Received: December 4, 2002

Dear Mr. Varty:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on March 4, 2003. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter as substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA) they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's applicable requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements

as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K024015

Device Name: Alliance Medical Corporation Reprocessed Endoscopic Trocars and Cannulas

Indications For Use: Reprocessed Endoscopic Trocars and Cannulas are indicated for use to establish a port of entry for endoscopic instruments in patients requiring minimally invasive surgical procedures.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

02/9/02

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K024015

The following list represents the specific Endoscopic Trocars and Cannulas to be reprocessed by Alliance Medical Corporation under this submission.

Manufacturer	Description	Model
US Surgical, Auto Suture	Surgiport Trocar w/ radiolucent (bladed)	171040
US Surgical, Auto Suture US Surgical, Auto Suture	Spring Grip Non-Conductive Spring Grip Non-Conductive	174102 174103
US Surgical, Auto Suture	Spring Grip Non-Conductive	174104
US Surgical, Auto Suture	Spring Grip Non-Conductive	174110
US Surgical, Auto Suture	Thoracoport Trocar	179301
US Surgical, Auto Suture	Thoracoport Trocar	179303
US Surgical. Auto Suture US Surgical, Auto Suture	Thoracoport Trocar Thoracoport Trocar	179305 179307 179315
Ethicon	ENDOPATH adjustable cannula	T355
Ethicon	ENDOPATH adjustable cannula	T511
Ethicon	ENDOPATH adjustable cannula	T512
Ethicon	Bladeless Trocar with Stability Sleeve, Non-handled	35NST
Ethicon	Bladeless Trocar with Smooth Sleeve, non-handled	35OS
Ethicon	Bladeless Trocar with Smooth Sleeve, handled	35HL
Ethicon	Bladeless Trocar with Smooth Sleeve, Non-handled	35OL
Ethicon	Bladeless Trocar with Stability Sleeve, Non-handled	35NLT
Ethicon	Bladeless Trocar with Smooth Sleeve, Handled	511H
Ethicon	Bladeless Trocar with Smooth Sleeve, Non-handled	511O
Ethicon	Bladeless Trocar with Stability Sleeve, Handled	511 HT
Ethicon	Bladeless Trocar with Stability Sleeve, Non-handled	511NT
Ethicon	Bladeless Trocar with Smooth Sleeve, Handled	512HN
Ethicon	Bladeless Trocar with Smooth Sleeve, Non-	512ON
Ethicon	Bladeless Trocar with Stability Sleeve, Handled	512HT
Ethicon	Bladeless Trocar with Stability Sleeve, Non-handled	512NT
Ethicon	Bladeless Trocar with Smooth Sleeve	5128
Ethicon	ENDOPATH Dilating Tip Trocar with Stability Sleeve	355SD
Ethicon	ENDOPATH Dilating Tip Trocar with Smooth Sleeve	355SM
Ethicon	ENDOPATH Dilating lip Trocar with Stability Sleeve	578SD
Ethicon	ENDOPATH Dilating Tip Trocar with Smooth Sleeve	511SM
Ethicon	ENDOPATH Dilating Tip Trocar with Stability Sleeve	511SD
Ethicon	ENDOPATH Dilating Tip Trocar with Stability Sleeve	512SD
Ethicon	ENDOPATH Dilating Tip Trocar with Smooth Sleeve	512SM
Ethicon	ENDOPATH Dilating Tip Trocar with Smooth Sleeve	512XD
Ethicon	ENDOPATH TRISTAR Trocar with Smooth Sleeve	355S
Ethicon	ENDOPATH TRISTAR Trocar with Integrated Stability Threads	355T
Ethicon	ENDOPATH TRISTAR Trocar with Smooth Sleeve	355L
Ethicon	ENDOPATH TRISTAR Trocar with Smooth Sleeve	511S
Ethicon	ENDOPATH TRISTAR Trocar with Smooth Sleeve	512S